drugs moving in the market. Action against any complaints for possible manufacture or sale of sub-standard drugs is taken by State Governments through their respective drugs control organizations. Samples of medicines are taken randomly by the Drugs Control Officers from the manufacturing and sales outlets to validate their quality in their drugs testing laboratories. The details of the names of the medicines of the pharmaceutical companies togetherwith results of analysis and punitive action thereof are maintained by the Drugs Controllers of States/UTs. Such details are, therefore, not maintained Centrally. However, as per the feedback, available from the Drugs Controller of States/UTs 38,824,36,314 and 40,682 samples were tested during the period 2001-02, 2002-03 and 2003-04, out of which 3,458, 3,395 and 3,499 samples were declared to be not of standard quality which is 8.9%, 9.34% and 8.60% respectively of the samples tested.

Indian patients used as Guinea Pigs for Clinical Trails

931. SHRI UDAY PRATAP SINGH: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware that the Indian Patients are being used as Guinea Pigs in Clinical Trials by some Bio-Tech Companies; and

(b) if so, the names of companies involved and action taken by DCGI against them?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) No specific instances about Indian patients used as guinea pigs in clinical trials by some bio-tech Companies has come to the knowledge of this Ministry.

All clinical trials including those of bio-tech products are required to be conducted as per norms prescribed under Drugs and Cosmetics Act and Rules framed thereunder and the Good Clinical Practices (GCP) Guidelines. Approval for clinical trials are also to be obtained from Ethical Committee of respective medical Institutions.

There was, however a news-item appearing in the Economic Times Dated 26th September, 2004, under the captain 'Guinea Pigs'. The report is however not based on facts. The trials mentioned in the news report had been conducted as per norms and evaluated by experts.